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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,142	08/25/2003	Robert Kaiser	PROL-001CON	3238

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EXAMINER

CHIN, CHRISTOPHER L

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/648,142	<b>Applicant(s)</b> KAISER ET AL.	
	<b>Examiner</b> Christopher L. Chin	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 10 are vague. In line 3 of each claim, the recitation of "the luminal surface" lacks antecedent support.

In claims 1, 10, 21, and 27, the term "a capture system on the luminal surface of the capillary tubing having the formula" is inconsistent with the formula which follows which already contains a "luminal surface" – S. It appears that the phrase "on luminal surface" should be deleted.

Claims 9 and 20 are incomplete and do not make sense.

Claim 21 is vague. In line 4, the recitation of "the luminal surface" lacks antecedent support.

Claim 27 is vague. In line 6, the recitation of "the luminal surface" lacks antecedent support. In line 5, "applied" should be replaced with --applying--. The claim is also confusing. The step of "contacting the particles" with "L" would presumably attach the particles to "L". In view of this first contacting step, it is not clear why there is a later step of "binding said desired particle subset to said ligand L" since this would duplicate the binding which already has taken place between "L" and "a moiety present on the particle subset".

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slowiaczek et al (U.S. Patent 5,763,194) or Muller (U.S. Patent 5,824,478) or Muller et al (U.S. Patent 5,804,384) in view of Goffe et al (WO 91/16116) or Miltenyi (WO 96/31776) or Cantor et al (U.S. Patent 5,849,878).

Slowiaczek et al, Muller, and Muller et al each disclose solid supports, including capillary tubes, in which the first member of a specific binding pair is attached to the tube. This immobilized first specific binding pair member is then used to bind and isolate its corresponding second specific binding pair member, which may be a cell from a sample. The attachment of the first specific binding pair member to the solid support capillary can be through any of a variety or combination of techniques which are well known in the art, for example, avidin-streptavidin, carbodiimide coupling, DNA linkers, amino linkage to the support, etc. See Slowiaczek et al: col. 2, lines 13-22; col. 3, lines 16-25; Muller: col. 5, lines 48-61; col. 7, lines 36-46; col. 8, line 43 - col. 9, line 52; Muller et al: col. 5, lines 19-36 and 55-60.

Slowiaczek et al, Muller, and Muller et al differ from the instant invention in failing to teach the use of a cleavable linker or cell binding ligands.

Goffe et al, Miltenyi, and Cantor et al disclose methods of separating cells from a sample using a solid support to which a cell-binding ligand is attached by conventional means which may include any of a variety or combination of techniques which are well known in the art, for example, avidin-biotin binding, amination of the solid support, use of heterobifunctional linkers, DNA linkers, etc. Enzyme cleavable DNA linkers for the purpose of releasing a second specific binding member are disclosed. See Goffe et al: page 1, lines 13-17; page 11, lines 3-11; Miltenyi: page 8, lines 13-26; page 5, lines 26-37; page 6, lines 1-8; Cantor et al: col. 4, lines 28-34; col. 19, Cell Binding Assays; col. 8, lines 55-57.

In view of the fact that the coupling of a wide variety of ligands to capillary tubes by conventional linking means for the purpose of separating the corresponding receptor from a sample is well known in the art, as taught by Slowiaczek et al, Muller, and Muller et al, it would have been obvious to substitute any of variety of ligands, including the cell binding ligands of Goffe et al, Miltenyi, and Cantor et al as the specific immobilized ligand on the capillary tubes of Slowiaczek et al, Muller, and Muller et al. The use of a cleavable linker, as claimed, is clearly taught by the prior art to be a conventional means for releasing captured second members of a specific binding pair from a solid support – see Muller at col. 9, lines 15-24.

With respect to claim 24, see Cantor et al at col. 8, lines 55-57 for the use of a nuclease as a cleavage reagent.

With respect to claim 27, see Muller at col. 7, lines 36-42 for the use of a cassette which reads on the binding of X' (avidin) moiety and the X" (biotin) moiety.

**Conclusion**

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following U.S. Patents disclose various capillary devices:

6,020,209; 5,707,799; 5,759,779; 5,675,155; and 5,439,578

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Christopher L. Chin*

Christopher L. Chin  
Primary Examiner  
Art Unit 1641

6/26/04